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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,746

10/08/2003

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02/09/2006

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,746	NIELAND ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/5/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicants' response, which included amendment to claims 1-4 and 10-11, filed on 11/28/2005, is made of record. Claims 1-17 are pending.

In view of applicants' response, the following apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same limitation

1. Recitation of "Table 1", in amended claim 1 renders claim 1 and its dependent claims indefinite as it is not clear what Table 1 is being referred to. whether the claim is compound claim or composition claim or a method of use claim. Claim 1 is indefinite as it refers to a Table of compounds which is not in the claims but in the disclosure. See MPEP 2173.05(s), which states:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim.

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Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

The same applies to claim 4 which also refers to Table 1.

2. Claim 2 is a duplicate of claim 1 as there is no material difference between claim 1 and claim 2. Note both have same scope as they rely on same pharmaceutical composition. Note intended use is not given any weight in such a pharmaceutical composition. Note In re Tuominen 213 USPQ 89. Also See Intirtool, LTD. V. Texar Corp., 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.'"

Instant claim is a composition claim of compound and the compound is clearly defined by a structure shown in Table 1. Omission of the attributes to the composition of the compounds of Table 1 would not alter the structure of these compounds and hence the composition. Although claim 2 depends on claim 1 and would share the functional limitation recited in claim1, a compound is a compound irrespective of is functional property.

3. Claim 5 is an improper depended claim as it depends on claim 4 for method of use and claim1 for pharmaceutical composition of active ingredient.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected 35 U.S.C 102(b) as being anticipated by ChemBridge DiverSet.

As acknowledged by the applicants the compounds of the Table 1 is from ChemBridge DiverSet and hence are known and available to public as evident from the Brochure provided by the applicants.

The Brochure clearly identifies the compound set as drugs and hence a pharmaceutical composition derived from them is clearly anticipated.

It is clear that these compounds are known compounds.

See also In re Best 195 USPQ 430. Particularly note In re Best has the following quote " Where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may, in fact, be an inherent characteristic in the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on". See MPEP 2112.

Since the instant claim is not a method of use claim, this rejection is proper.

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Claims 10-17 are rejected 35 U.S.C 102(b) as being anticipated by Krieger et al., US2002/0099040.

Krieger et al., teaches several SR-B1 antagonists and their use, which include generically claimed instant compound and the method of use.

See entire document. Especially see pages 2-10, paragraphs 0012 to 0112 for details of the SR-B1, HDL, cholesterol transport, compounds that interact with SR-B1 or alter its expression, inhibition of uptake, binding or transport to SR-B1, screening assay, Northern analysis as well as pages 10-16 for examples 1-6. Note teachings of Krieger in these pages meet all the limitations claimed in claims 10-17.

Contrary to applicants' urging Krieger et al. is a valid prior art as applicant's earliest priority to the provisional application is not proper as it does not include all the compounds of Table 1.

In addition as, as recited, the instant claims does not include any compounds.

Hence this rejection as applied to screening is maintained.

Claims 10-17 are rejected 35 U.S.C 102(b) as being anticipated by Acton US 5,965,790

Acton teaches several compounds that alter SR-B1 expression, its role in lipid transfer, cholesterol transport along with screening assays for discovering drugs that regulate the expression of Sr-B1. See entire document. Especially see column 1-14 for details of SR-B1 and its role in lipid and cholesterol transport. Particularly see column 9-10 for small molecules that interact with the gene and regulate Sr-B1 expression as well as column 12-31 for various assays for screening and evaluating such compounds. See

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claims 18-24 for the same. Note all the compounds taught by Acton are also generically claimed in the instant claims 1 and all the limitations recited in claims 10-17 are also taught by Acton.

Contrary to applicants' urging Acton et al. is a valid prior art as applicants' earliest priority to the provisional application is not proper as it does not include all the compounds of Table 1. In addition as, as recited, the instant claims does not include any compounds. Furthermore, Action in column 26-28 clearly teaches screening assays and high-thorough screening.

Hence this rejection as applied to screening is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

2/6/2006